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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

17P21PCT/US

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Application Number

10519988

Filed

7/25/2005

First Named Inventor

Dieter Scharnweber

Art Unit

1637

Examiner

Young J. Kim

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

attorney or agent of record.

Registration number 35747

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

Gudrun E. Huckett
Signature

Gudrun E. Huckett

Typed or printed name

+49-202-2570371

Telephone number

6/4/2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

*Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dieter Scharnweber et al.
Serial No: 10/519,988
Filed: 1/4/2005
Title: Metallic Object with a Nucleic Acid Coating and Derivatives Thereof and
Method for Producing Said Object
Examiner: Young J. Kim
Art Unit: 1637

Commissioner for Patents

Alexandria, VA 22313-1450

**ARGUMENTS ACCOMPANYING
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Claims 23-30, 32, 33, 35, 36 are rejected under 35 USC 102(b) as being anticipated by *Bitner* (EP0391608). Claim 31 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Bitner* in view of *Wengel et al.* (US 6,670,461). Claim 34 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Bitner* in view of *Yabusaki et al.* (WO 85/02628).

The examiner argues that *Bitner* discloses a solid support comprising an amount of metal oxide (i.e., a metallic object) with a coating that is comprised of a thin metal oxide layer as disclosed on page 3, line 20; page 4, line 16; page 7, lines 15-16; and nucleic acid molecules having their 5'-terminal or 3'-terminal ends incorporated into the metal oxide layer as disclosed on page 3, lines 22-23. Claim 23 is thus anticipated in examiner's opinion.

In response to applicant's arguments, examiner has stated that claim 23 does not require the terminal ends to be incorporated but instead the claim reads "terminal areas". Further, examiner asserts that it would certainly be the 5' or 3' terminal areas of the DNA in *Bitner* that are sorbed onto the metal oxide surface. Further examiner states that

it is inconceivable that not a single nucleic acid in accordance with the method of *Bitner* would sorb to the metal oxide layer especially because hybridization is addressed by *Bitner* on page 14, lines 13-14. In response to applicant's statement that the only disclosure as regards the sorption is on page 3 of *Bitner*, examiner refers to page 14 and page 10 of *Bitner* as addressing sorption. In response to applicant's statement that *Bitner* proposes that the backbone is the sorption location, examiner argues that this disclosure is not an absolute statement and cannot be construed as excluding sorption of the 5' and 3' ends.

Examiner's contention that the claim language "3' terminal molecule area" or "5' terminal molecule area" is not equivalent to 3' or 5' terminal ends as argued and that therefore the entire argument presented by applicant is not persuasive is believed to be unfounded. The language "3' terminal" or "5' terminal" (terminal = end) specifies a very distinct part of the sugar ring of the DNA molecule so that there can be no question as to where the 5' terminal molecule area or 3' terminal molecule area is.

Applicant would like to stress again that *Bitner* mentions nowhere in the entire reference the 5'-terminal or 3'-terminal ends (or areas) of DNA or their incorporation into or sorption to the metal oxide layer or coating. The 5'-terminal or 3'-terminal ends or areas of the nucleic acids are never *verbatim* mentioned in this reference. It is only disclosed that the DNA molecules do sorb to the metal oxide surface but not how.

The examiner specifically refers to page 3, lines 22-23 (it appears that examiner meant to refer to lines 21-22) as stating that the 5' or 3' ends are sorbed or incorporated. This is not so. The two lines read:

"(b) nucleic acids sorbed to at least a portion of the available surface of the support in a manner such that the nucleic acid substantially retains biological accessibility and reactivity."

Nothing is said in this text portion **how** the nucleic acid is sorbed or **which part** of the nucleic acid sorbs to the surface. The 5' terminal or 3' terminal ends or areas are not mentioned. Nothing is said on pages 10 or 14 in regard to the the 5' terminal or 3' terminal ends being sorbed. Only the fact that the DNA is SORBED - **not how it is sorbed** - is set forth on pages 10 and 14 of *Bitner* in the examples provided here. Nothing in the entire reference refers to sorption through the 3' terminal or 5' terminal ends or areas. Examiner has not provided any evidence that **5'-terminal or 3'-terminal molecule areas** are indeed

sorbed to metal oxide surfaces in *Bitner*.

The examiner states in regard to claim 24 that the nucleic acid according to *Bitner* retains biological accessibility and reactivity, i.e, hybridization (examiner refers to page 14, lines 13-14, of *Bitner* where there is simply stated that DNA is used for hybridization). However, hybridization capability allows no conclusion whether the nucleic acid is sorbed to the surface of the metal oxide by the 5'-terminal or 3'-terminal ends or by its backbone; immobilization of the nucleic acid by way of the backbone is sufficient for enabling hybridization.

Moreover, *Bitner* discloses that the phosphate groups of the DNA backbone may play a significant role in the sorption of the nucleic acids to the metal oxide (page 5, lines 32-33). Thus, the only teaching to be derived is that *Bitner* believes the backbone to be the part sorbing to the metal oxide and not that the 5' terminal or 3' terminal ends (or areas) sorb to metal oxide. The fact that *Bitner* believes or states that the DNA sorbs via the backbone and the fact that *Bitner* describes that the sorbed DNA retains biological accessibility and reactivity is further evidence that examiner's contention that hybridization requires 3' terminal or 5' terminal sorption is wrong - *Bitner* only allows the conclusion that the DNA is backbone-sorbed and is capable of hybridization.

It is respectfully submitted that *Bitner* discloses only two things:

- DNA sorbs to metal oxide surfaces;
- the backbone is believed to play a significant role in sorption of the nucleic acid to the metal oxide surface.

Based on this disclosure there cannot be anticipation of the subject matter as claimed in claim 23 - *Bitner* simply does not disclose sorption through the 5' terminal or 3' terminal ends (or areas). Even if the 5' terminal ends or the 3' terminal ends would sorb, as asserted by the examiner without any evidence being provided, the claim language of claim 23 is not anticipated. Claim 23 specifically sets forth:

"... wherein the nucleic acid compounds have 5'-terminal or 3'-terminal molecule areas and wherein the 5'-terminal or 3'-terminal molecule areas are **embedded in the metal oxide layer grown about the 5'-terminal or 3'-terminal molecule areas.**"

The claim sets forth not only sorption, as stated by the examiner in the office action, but **embedding in the oxide layer that is grown about the 5'-terminal or 3'-terminal**

molecule areas. **Sorption** is not equivalent to embedding as sorption is a physical process that is reversible. The present invention requires embedding in the metal oxide layer, the metal oxide layer being grown about the terminal areas. *Bitner* does not disclose that metal oxide is being grown about the terminal ends or terminal areas in order to embed the terminal areas in the metal oxide.

Applicant would like to stress that the gist of the invention is that the 5'-terminal or 3'-terminal ends (areas) are “incorporated” or, as now more specifically defined in claim 23, are **embedded in the metal oxide layer that is grown about the 5'-terminal or 3'-terminal molecule areas**; see in particular Fig. 2 where embedding in the metal oxide is shown. The 5'-terminal or 3'-terminal molecule areas are not merely **sorbed** to the surface but are **embedded in the growing metal oxide layer** (see page 4, 1st full paragraph, of the specification). The nucleic acids according to the present invention are fixed in the metal oxide and cannot be removed.

The sorbed nucleic acids of *Bitner* however can be desorbed (see page 8, lines 42-46, of *Bitner* where the **desorption** of the nucleic acids is described as an important attribute of the disclosed composition) and there is no teaching in regard to embedding the sorbed portions in the metal oxide layer grown about the ends.

The present invention provides a regio-selective incorporation of the nucleic acids by means of the 5'-terminal or 3'-terminal areas and, in this way, the unincorporated sections are freely movable. This makes them accessible for the hybridization reactions and also for biological processes in which the secondary and tertiary structures of the nucleic acids are important. See particularly page 4, 2nd to 4th full paragraphs, of the instant specification.

In summarizing the above, *Bitner* neither discloses or suggest sorption by means of 5' terminal or 3' terminal areas and only refers to the backbone being important for adsorption; *Bitner* does not disclose that the 5' terminal or 3' terminal ends (or areas) are embedded in a metal oxide layer grown about these ends (or areas).

Claim 23 is therefore neither anticipated nor obvious in view of *Bitner* and should be allowable together with its dependent claims.

Reconsideration and withdrawal of the rejection of the claims under 35 USC 102 are therefore respectfully requested.

Claims 23-26 are rejected on the ground of obviousness-type double patenting over US 6,524,718. The instant application is assigned to Technische Universität Dresden, Dresden, Germany. The cited patent was first assigned by the inventors to Merck Patent GmbH, Darmstadt, Germany, and then assigned to Biomet Deutschland GmbH, Berlin, Germany. There is no common ownership. According to MPEP 804 (Heading B. Nonstatutory Double Patenting 1. Obviousness-Type, 1st paragraph):

"Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject **matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement** as set forth in 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent." (Emphasis added.)

There is no common ownership and no joint research agreement. There is no unjustified extension of term of the right to exclude.

Reconsideration and withdrawal of the double patenting rejection of the claims 23-26 are therefore respectfully requested.

Respectfully submitted on June 4, 2008,

/Gudrun E. Huckett/

Ms. Gudrun E. Huckett, Ph.D.
Patent Agent, Registration No. 35,747
Schubertstr. 15a
42289 Wuppertal
GERMANY
Telephone: +49-202-257-0371
Facsimile: +49-202-257-0372
gudrun.draudt@t-online.de

GEH